



Patent  
Attorney Docket No. 033292-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Scarampi Sebastiano et al.

Application No.: 10/751,276

Filing Date: January 2, 2004

Title: GILSONITE DERIVED PHARMACEUTICAL DELIVERY COMPOSITIONS AND METHODS

Group Art Unit: 1616

Examiner: Unassigned

Confirmation No.: 7478

INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is a First Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- ☐ Charge \_\_\_\_\_ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By

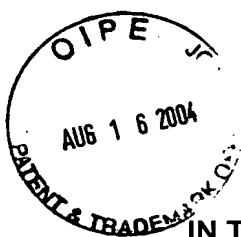
T. Gene Dillahunt

Registration No. 25,423

Date:

8/9/04

(4/04)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
Sebastiano Scarampi et al.	)	Group Art Unit: 1616
	)	
Application No.: 10/751,276	)	Examiner: Unassigned
	)	
Filed: January 2, 2004	)	Confirmation No.: 7478
	)	
For: GILSONITE DERIVED	)	
PHARMACEUTICAL DELIVERY	)	
COMPOSITIONS AND METHODS	)	
	)	
	)	

**FIRST INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

**U.S. Patent Documents**

3,472,931	514/50	Stoughton	10/69
3,527,864	424/59	Kilmer MacMillan et al.	9/70
3,598,122	424/435	Zaffaroni	8/71
3,598,123	424/435	Zaffaroni	8/71
3,731,683	424/434	Zaffaroni	5/73
3,797,494	424/434	Zaffaroni	3/74
3,896,238	514/777	Smith	7/75
3,903,256	424/59	MacMillan et al.	9/75

U.S. Patent Documents (Cont.)

3,952,099	260/310	Mackille	4/76
4,046,886	424/227	Smith	9/77
4,130,643	424/238	Smith	12/78
4,130,667	424/361	Smith	12/78
4,286,592	128/260	Chandrasekaran	9/81
4,299,826	424/181	Luedders	11/81
4,314,557	128/260	Chandrasekaran	2/82
4,316,893	424/180	Rajadhyaksha	2/82
4,335,115	424/181	Thompson et al.	6/82
4,343,798	424/240	Fawzi	8/82
4,379,454	604/897	Campbell et al.	4/83
4,405,616	424/244	Rajadhyaksha	9/83
4,424,210	424/180	Rajadhyaksha	1/84
4,435,180	604/896	Leeper	3/84
4,559,222	424/28	Enscore et al.	12/85
4,568,343	604/896	Leeper	2/86
4,573,999	623/7	Netto	3/86
4,588,580	424/21	Gale et al.	5/86
4,645,502	604/896	Gale et al.	2/87
4,704,282	424/449	Campbell et al.	11/87

U.S. Patent Documents (Cont.)

4,746,515	424/449	Cheng et al.	5/88
4,764,379	424/449	Sanders et al.	8/88
4,788,062	424/449	Gale et al.	11/88
4,792,571	514/773	Schiltz et al.	12/88
4,816,258	424/448	Nedberge et al.	3/89
4,820,720	514/356	Sanders et al.	4/89
4,849,224	424/434	Chang et al.	7/89
4,849,226	424/448	Gale	7/89
4,863,738	424/449	Taskovich	9/89
4,863,970	514/784	Patel et al.	9/89
4,865,848	424/449	Cheng et al.	9/89
4,900,555	424/449	Cheng et al.	2/90
4,908,027	604/890	Enscore et al.	3/90
4,940,586	424/464	Cheng et al.	7/90
4,943,435	424/448	Baker et al.	7/90
4,973,468	424/449	Chiang et al.	11/90
4,983,395	424/448	Chang et al.	1/91
5,004,610	424/448	Osborne et al.	4/91
5,006,342	424/445	Cleary et al.	4/91
5,026,556	424/449	Drust et al.	6/91
5,053,227	424/448	Chiang et al.	10/91

U.S. Patent Documents (Cont.)

5,059,426	424/449	Chiang et al.	10/91
5,149,538	424/449	Granger et al.	9/92
5,152,997	424/449	Ebert et al.	10/92
5,229,441	524/64	Romagosa et al.	7/93
5,302,395	424/449	Ebert et al.	4/94
5,312,122	280/33.992	Doty	5/94
5,314,694	424/448	Gale et al.	5/94
5,352,456	424/448	Fallon et al.	10/94
5,378,730	514/535	Lee et al.	1/95
5,411,740	424/448	Lee et al.	5/95
5,629,019	424/489	Lee et al.	5/97
5,641,504	424/447	Lee et al.	6/97
5,643,899	514/171	Elias et al.	7/97
5,650,165	424/448	Akemi et al.	7/97
5,686,097	424/448	Taskovich et al.	11/97
5,723,114	424/78.02	Thornfeldt et al.	3/98
5,747,069	424/484	Asakura et al.	5/98
5,760,096	514/946	Thornfeldt et al.	6/98
5,788,984	424/449	Guenther et al.	8/98
5,843,468	424/448	Burkoth et al.	12/98
5,885,565	424/78.02	Elias et al.	3/99

U.S. Patent Documents (Cont.)

5,900,250	424/448	Lee et al.	5/99
5,912,009	424/448	Venkateshwaran et al.	6/99
5,952,000	424,448	Venkateshwaran et al.	9/99
6,010,691	424/78.02	Thornfeldt et al.	1/00
6,054,433	514/25	Elias et al.	4/00
6,060,515	514/560	Elias et al.	5/00
6,071,955	514/475	Elias et al.	6/00
6,184,215	514/182	Elias et al.	2/01
6,187,814	514/531	Elias et al.	2/01
6,190,894	435/183	Thornfeldt et al.	2/01
6,248,348	424/448	Landrau et al.	6/01
6,267,984	424/449	Beste et al.	7/01

Foreign Patent Documents

2,001,688	Canada	4/27/91
-----------	--------	---------

Non-Patent Literature Documents

Auchter G., et al., "Acrylic Adhesives," in *Handbook of Pressure Sensitive adhesive Technology*, D. Satas, Ed. (Satas & Associates, Warwick, RI, 3d ed., 1999) pp. 444-514

Cantor, Adam S., "Novel Acrylate Adhesives for Transdermal Drug Delivery," *Pharmaceutical Technology*, Jan. 2002, 9 pages.

Dekker, Marcel "Transdermal Drug Delivery" (*Drugs and the Pharmaceutical Sciences* by Richard H. Guy (Editor), Jonathan Hadgraft (Editor) 2nd Rev & ex edition

imas, Dimitrios A., et al. "Effect of Several Factors on the Mechanical Properties of Pressure-Sensitive Adhesives Used in Transdermal Therapeutic Systems" *AAPS PharmSciTech*, 2000; 1 (2) article 16

Reinl, H.M., et al., "Time-resolved infrared ATR measurements of liposome transport kinetics in human keratinocyte cultures and skin reveals a dependence on liposome size and phase state," *J Invest Dermatol* 1995, Aug: 105(2):291-5 (Abstract only)

Remington: *The Science and Practice of Pharmacy*, 19th Ed. (Easton, PA.: Mack Publishing Co., 1995)

Remington: *The Science and Practice of Pharmacy*, 19th Ed. (Easton, PA.: Mack Publishing Co., 1995) pp. 1399-1404

Santus et al., "Transdermal Enhancer Patent Literature" *Journal of Controlled Release*, pp. 1-20 (1993)

Venkatraman, S. and Gale, R., "Skin Adhesives and Skin Adhesion, Part I: Transdermal Drug Delivery Systems," *Biomaterials* 19, 1119-1136 (1998)

"Dermatological and Transdermal Formulations: *Drugs and the Pharmaceutical Sciences*, vol. 119 by Kenneth A. Walters (Editor)

Williams et al., "Skin Absorption Enhancers" Critical Review in *Therapeutic Drug Carrier Systems*, pp. 305-353 (19920

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

To assist the Examiner, the document is / documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date

8/9/04

By:

T. Gene Dillahunt

T. Gene Dillahunt  
Registration No. 25,423  
Redwood Shores, California Office  
(650) 622-2300

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

**FIRST  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/751,267
Filing Date	January 2, 2004
First Named Inventor	Sebastiano Scarampi et al.
Examiner Name	Unassigned
Attorney Docket Number	033292-004

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	3,472,931	514/50	Stoughton	10/69
	3,527,864	424/59	Kilmer MacMillan et al.	9/70
	3,598,122	424/435	Zaffaroni	8/71
	3,598,123	424/435	Zaffaroni	8/71
	3,731,683	424/434	Zaffaroni	5/73
	3,797,494	424/434	Zaffaroni	3/74
	3,896,238	514/777	Smith	7/75
	3,903,256	424/59	MacMillan et al.	9/75
	3,952,099	260/310	Mackille	4/76
	4,046,886	424/227	Smith	9/77
	4,130,643	424/238	Smith	12/78
	4,130,667	424/361	Smith	12/78
	4,286,592	128/260	Chandrasekaran	9/81
	4,299,826	424/181	Luedders	11/81
	4,314,557	128/260	Chandrasekaran	2/82
	4,316,893	424/180	Rajadhyaksha	2/82
	4,335,115	424/181	Thompson et al.	6/82
	4,343,798	424/240	Fawzi	8/82
	4,379,454	604/897	Campbell et al.	4/83
	4,405,616	424/244	Rajadhyaksha	9/83
	4,424,210	424/180	Rajadhyaksha	1/84
	4,435,180	604/896	Leeper	3/84
	4,559,222	424/28	Enscore et al.	12/85
	4,568,343	604/896	Leeper	2/86
	4,573,999	623/7	Netto	3/86
	4,588,580	424/21	Gale et al.	5/86
	4,645,502	604/896	Gale et al.	2/87
	4,704,282	424/449	Campbell et al.	11/87
	4,746,515	424/449	Cheng et al.	5/88
	4,764,379	424/449	Sanders et al.	8/88
	4,788,062	424/449	Gale et al.	11/88
	4,792,571	514/773	Schiltz et al.	12/88
	4,816,258	424/448	Nedberge et al.	3/89
	4,820,720	514/356	Sanders et al.	4/89
	4,849,224	424/434	Chang et al.	7/89
	4,849,226	424/448	Gale	7/89
	4,863,738	424/449	Taskovich	9/89
	4,863,970	514/784	Patel et al.	9/89
	4,865,848	424/449	Cheng et al.	9/89
Examiner Signature			Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	10/751,267
Filing Date	January 2, 2004
First Named Inventor	Sebastiano Scarampi et al.
Examiner Name	Unassigned
Attorney Docket Number	033292-004

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	4,900,555	424/449	Cheng et al.	2/90
	4,940,586	424/464	Cheng et al.	7/90
	4,943,435	424/448	Baker et al.	7/90
	4,973,468	424/449	Chiang et al.	11/90
	4,983,395	424/448	Chang et al.	1/91
	5,004,610	424/448	Osborne et al.	4/91
	5,006,342	424/445	Cleary et al.	4/91
	5,026,556	424/449	Drust et al.	6/91
	5,053,227	424/448	Chiang et al.	10/91
	5,059,426	424/449	Chiang et al.	10/91
	5,149,538	424/449	Granger et al.	9/92
	5,152,997	424/449	Ebert et al.	10/92
	5,229,441	524/64	Romagosa et al.	7/93
	5,302,395	424/449	Ebert et al.	4/94
	5,312,122	280/33.992	Doty	5/94
	5,314,694	424/448	Gale et al.	5/94
	5,352,456	424/448	Fallon et al.	10/94
	5,378,730	514/535	Lee et al.	1/95
	5,411,740	424/448	Lee et al.	5/95
	5,629,019	424/489	Lee et al.	5/97
	5,641,504	424/447	Lee et al.	6/97
	5,643,899	514/171	Elias et al.	7/97
	5,650,165	424/448	Akemi et al.	7/97
	5,686,097	424/448	Taskovich et al.	11/97
	5,723,114	424/78.02	Thornfeldt et al.	3/98
	5,747,069	424/484	Asakura et al.	5/98
	5,760,096	514/946	Thornfeldt et al.	6/98
	5,788,984	424/449	Guenther, et al.	8/98
	5,843,468	424/448	Burkoth et al.	12/98
	5,885,565	424/78.02	Elias et al.	3/99
	5,900,250	424/448	Lee et al.	5/99
	5,912,009	424/448	Venkateshwaran, et al.	6/99
	5,952,000	424/448	Venkateshwaran, et al.	9/99
	6,010,691	424/78.02	Thornfeldt et al.	1/00
	6,054,433	514/25	Elias et al.	4/00
	6,060,515	514/560	Elias et al.	5/00
	6,071,955	514/475	Elias et al.	6/00
	6,184,215	514/182	Elias et al.	2/01
	6,187,814	514/531	Elias et al.	2/01
	6,190,894	435/183	Thornfeldt et al.	2/01
	6,248,348	424,448	Landrau et al.	6/01

Examiner Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**FIRST  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3**Complete if Known**

Application Number	10/751,267
Filing Date	January 2, 2004
First Named Inventor	Sebastiano Scarampi et al.
Examiner Name	Unassigned
Attorney Docket Number	033292-004

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	6,267,984	424/449	Beste et al.	7/01

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
	2,001,688		Canada	4/27/91		

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Auchter G., et al., "Acrylic Adhesives," in <i>Handbook of Pressure Sensitive adhesive Technology</i> , D. Satas, Ed. (Satas & Associates, Warwick, RI, 3d ed., 1999) pp. 444-514
	Cantor, Adam S., "Novel Acrylate Adhesives for Transdermal Drug Delivery," <i>Pharmaceutical Technology</i> , Jan. 2002, 9 pages.
	Dekker, Marcel "Transdermal Drug Delivery" ( <i>Drugs and the Pharmaceutical Sciences</i> by Richard H. Guy (Editor), Jonathan Hadgraft (Editor) 2nd Rev & ex edition
	Dekker, Marcel "Mechanisms of Transdermal Drug Delivery" <i>Drugs and the Pharmaceutical Sciences</i> , Vol 83, edited by Russell O. Potts and Richard H. Guy (1997)
	Dimas, Dimitrios A., et al. "Effect of Several Factors on the Mechanical Properties of Pressure-Sensitive Adhesives Used in Transdermal Therapeutic Systems" <i>AAPS PharmSciTech</i> , 2000; 1 (2) article 16
	Reinl, H.M., et al., "Time-resolved infrared ATR measurements of liposome transport kinetics in human keratinocyte cultures and skin reveals a dependence on liposome size and phase state," <i>J Invest Dermatol</i> 1995, Aug; 105(2):291-5 (Abstract only)
	Remington: <i>The Science and Practice of Pharmacy</i> , 19th Ed. (Easton, PA.: Mack Publishing Co., 1995)
	Remington: <i>The Science and Practice of Pharmacy</i> , 19th Ed. (Easton, PA.: Mack Publishing Co., 1995) pp. 1399-1404
	Santus et al., "Transdermal Enhancer Patent Literature" <i>Journal of Controlled Release</i> , pp. 1-20 (1993)
	Venkatraman, S. and Gale, R., "Skin Adhesives and Skin Adhesion, Part I: Transdermal Drug Delivery Systems," <i>Biomaterials</i> 19, 1119-1136 (1998)
	"Dermatological and Transdermal Formulations: <i>Drugs and the Pharmaceutical Sciences</i> , vol. 119 by Kenneth A. Walters (Editor)
	Williams et al., "Skin Absorption Enhancers" Critical Review in <i>Therapeutic Drug Carrier Systems</i> , pp. 305-353 (19920

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.